

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of : Jeffrey M. Leiden
Application No: Not Yet Assigned
Filed: July 8, 2003
For: Long Term Expression of Gene Products
Docket No: 104914-159

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22213-1450

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M. Lisa Wilson

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form.

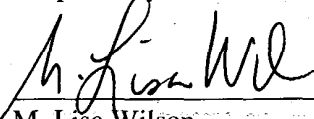
A copy of each of the documents listed on the attached PTO-1449 Form can be found in the parent application, U.S. Serial No. 09/091,134, filed June 23, 1998, or is included herewith.

This Information Disclosure Statement is being submitted before the mailing date of a first office action on the merits. Accordingly, no fee is due. The Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219 for consideration of this Information Disclosure Statement.

Applicants respectfully request that the Examiner initial and return a copy of the enclosed PTO-1449 Form with the next communication from the Patent Office.

Respectfully submitted,

Date: July 8, 2003


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Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>			Docket Number (Optional) 104914-159		Application Number Not Yet Assigned	
			Applicant, Jeffrey M. Leiden			
			Filing Date		Group Art Unit Not Yet Assigned	

U. S. Patent Documents						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,962,313	10/5/99	Podsakoff <i>et al.</i>			
	5,858,351	1/12/99	Podsakoff <i>et al.</i>			
	5,846,528	12/8/98	Podsakoff <i>et al.</i>			
	5,693,622	12/2/97	Wolff <i>et al.</i>			
	5,580,859	12/3/96	Felgner <i>et al.</i>			

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
	WO 95/13376	5/18/95	WO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	Barr <i>et al.</i> (1995) Gene Ther. 2:151-155, "Strain related variations in adenovirally mediated transgene expression from mouse hepatocytes in vivo: comparisons between immunocompetent and immunodeficient inbred strains".	
	Barr <i>et al.</i> (1994) Gene Ther. 1:51-58, "Efficient catheter-mediated gene transfer into the heart using replication-defective adenovirus".	
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	Brody <i>et al.</i> (1994) Human Gene Ther. 5:821-836, "Acute Responses of Non-Human Primates to Airway Delivery of an Adenovirus Vector Containing the Human Cystic Fibrosis Transmembrane Conductance Regulator cDNA".	
	Dai <i>et al.</i> (1995) PNAS USA 92:1401-5, "Cellular and humoral immune responses to adenoviral vectors containing factor IX gene: Tolerization of factor IX and vector antigens allows for long-term expression".	
	Dai <i>et al.</i> (1992) PNAS USA 89:10892-5, "Gene therapy via primary myoblasts: Long-term expression of factor IX protein following transplantation in vivo".	
	Dhawan <i>et al.</i> (1991) Science 254:1509-1512, "Systemic Delivery of Human Growth Hormone by Injection of Genetically Engineered Myoblasts".	
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	EXAMINER	DATE CONSIDERED
	EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy with next communication to applicant.	

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	Friedmann, T. (1997) Sci. Am. 96-101, "Overcoming the obstacles to gene therapy".		
	Hamamori <i>et al.</i> (1995) J. Clin. Invest. 95:1808-1813, "Myoblast Transfer of Human Erythropoietin Gene in a Mouse Model of Renal Failure".		
	Hamamori <i>et al.</i> (1994) Hum. Gene Ther. 5:1349-1356, "Persistent Erythropoiesis by Myoblast transfer of Erythropoietin cDNA".		
	Kass <i>et al.</i> (1994) Gene Ther. 1:395-402, "The impact of developmental stage, route of administration and the immune system on adenovirus-mediated gene transfer".		
	Kay <i>et al.</i> (1994) PNAS USA 91:2353-7, "In vivo hepatic gene therapy: Complete albeit transient correction of factor IX deficiency in hemophilia B dogs".		
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	Manthorpe <i>et al.</i> (1993) Hum. Gene Ther. 4:419-31, "Gene Therapy by Intramuscular Injection of Plasmid DNA: Studies on Firefly Luciferase Gene Expression in Mice".		
	Mastrangeli <i>et al.</i> (1996) Hum. Gene Ther. 7:79-87, "'Sero-Switch' Adenovirus-Mediated In Vivo Gene Transfer: Circumvention of Anti-Adenovirus Humoral Immune Defenses Against Repeat Adenovirus Vector Administration by Changing the Adenovirus Serotype".		
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	Morgan, J.E. (1994) Hum. Gene Ther. 5:165-73, "Cell and Gene Therapy in Duchenne Muscular Dystrophy".		
	Orkin and Motulsky (1995) "Report and recommendations of the panel to assess the NIH investment in research on gene therapy".		
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	Partridge <i>et al.</i> (1989) Nature 337:176-179, "Conversion of mdx myofibres from dystrophin-negative to -positive by injection of normal myoblasts".		
	Raz <i>et al.</i> (1993) Proc. Natl. Acad. Sci. USA 90:4523-4527, "Systemic immunological effects of cytokine genes injected into skeletal muscle".		
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	Tripathy <i>et al.</i> (1996) Nature Med. 2:545-550, "Immune responses to transgene-encoded proteins limit the stability of gene expression after injection of replication-defective adenovirus vectors".		
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	Verma <i>et al.</i> (1997) Nature 389:239-242, "Gene therapy – promises, problems and prospects".		
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	Wolff <i>et al.</i> (1992) Hum. Mol. Gen. 1:363-9, "Long-term persistence of plasmid DNA and foreign gene expression in mouse muscle".		
	Wolff <i>et al.</i> (1990) Science 247:1465-1468, "Direct Gene Transfer into Mouse Muscle in Vivo".		
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